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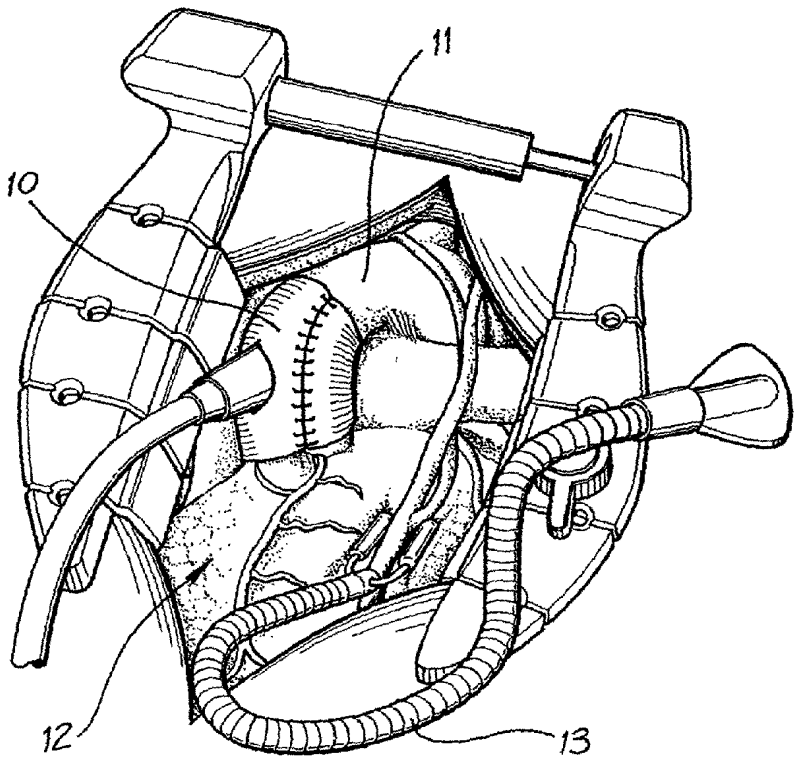
(54) Title: A METHOD OF PERFORMING A CORONARY ARTERY BYPASS OPERATION ON A PATIENT'S BEATING HEART




(57) Abstract: A method for the conduct of a beating heart coronary artery bypass operation on a patient. The method including application of extra-oartic counterpulsation to the aorta (11) of the patient for at least a part of the duration of the application

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# A METHOD OF PERFORMING A CORONARY ARTERY BYPASS OPERATION ON A PATIENT'S BEATING HEART

## Field of the Invention

The present invention relates to a method of performing a coronary artery bypass operation on a patient's beating heart. More specifically, the present invention relates to the performance of such an operation involving application of a extra-aortic counterpulsation pressure to the patient's arterial circulation.

## Background of the Invention

Off-pump coronary artery bypass surgery is a surgery technique in which the coronary artery bypass surgery is performed on the beating heart and avoids the need for a heart-lung bypass machine. This technique has evolved rapidly since 1998 and now accounts for 20% of all coronary artery bypass operations in the U.S.A. (Mack MJ, Coronary Surgery: off-pump and port access. Surg Clin North Am 2000 Oct; 80(5): 1575-91). Off-pump coronary bypass surgery has significant advantages over using a heart-lung machine, particularly by avoiding contact between blood and foreign surfaces of the tubing and oxygenator used in the bypass circuit.

A heart-lung machine typically also induces a massive inflammatory response, with subsequent fluid shifts, and in combination with a large amount of heparin required to avoid clotting, causes higher blood losses and then increased need for blood product transfusions (Macata BM, *et al.* Off-pump bypass graft operation significantly reduces oxidative stress and inflammation. Ann Thorac Surg 2000; 69(3):785-91). Also clearly evident, is dramatically lower cerebral emboli counts in off-pump coronary artery bypass patients (Diegeler A *et al.* Neuromonitoring and neurocognitive outcome in off-pump versus conventional coronary bypass surgery. Ann Thorac Surg 2000;69(4):1162-6; Watters MP *et al.* Reduced cerebral embolic signals in beating heart coronary surgery detected by transcranial Doppler ultrasound. Ann Thorac Surg 2000;70(2):466-72; Bowles BJ *et al.* Coronary artery bypass performed without the use of cardiopulmonary bypass is associated with reduced cerebral microemboli and improvided clinical results. Chest. 2001 Jan;119(1):1).

Off-pump coronary artery bypass procedure cannot be used in a cohort of patients with poor coronary performance, particularly in patients with unstable angina, severe left main coronary artery disease or triple vessel disease, post-infact angina, ischaemic

dysrhythmias, poor left ventricular function or cardiomyopathy. It would be desirable to be able to use such proceedures in these patients.

Intra-aortic balloon (IAB) counterpulsation has very recently been used for providing cardiac support during off-pump coronary artery bypass surgery. It is known, for example, that the effects of such intra-aorta balloon counterpulsation is particularly good for reducing left ventricular afterload, increasing diastolic coronary artery blood flow, and improving cardiac output (Katz ES, *et al.* Observations of coronary flow augmentation and balloon function during intra-aortic balloon counterpulsation using transoesophageal echocardiography. Am J Cardio 1992;69(19):1635-9). The IAB is inserted via a puncture in the femoral artery and the balloon is positioned in the descending thoracic aorta. The balloon is inflated during diastole (the period the heart is re-filling) to cause "diastolic blood pressure augmentation", which results in a higher mean blood pressure and is particularly important for maintaining adequate perfusion of important tissues highly dependent on oxygen, such as the brain and left ventricle. The diastolic augmentation also causes increased forward displacement of blood (cardiac output), particularly noticeable in the coronary arteries, which supply blood to the heart. The blood flow to the heart muscle can be increased by 50-100%, helping to flush away the products of ischemic catabolism, and improve muscle function. Furthermore, the balloon is deflated just as the heart is about to eject blood again, having the effect of reducing the "load" against which the heart must eject. This "unloading" effect also helps to (a) reduce the work of the left ventricle and (b) improve the cardiac output.

Intra-aortic balloon counterpulsation has been successfully used to support high-risk angioplasty patients and to enhance cardiac performance and reduce peri-operative risk in the context of high-risk heart surgery (Aguirre FV *et al.* Intra-aortic balloon pump support during high-risk coronary angioplasty. Cardiology 1994;84(3):175-86; Christenson JT *et al*). The effect of preoperative intra-aortic balloon pump support in patients with coronary artery disease, poor left-ventricular function (LVEF<40%), and hypertensive LV hypertrophy. J Thorac Cardiovasc Surg 1997;45(2):60-4). Recently, IAB counterpulsation support of cardiac function as a perioperative strategy for off-pump coronary artery bypass surgery has been demonstrated to be of significant benefit in high-risk patients (Kim KB *et al.* Intra-aortic balloon pump therapy facilitates posterior vessel off-pump coronary artery bypass grafting in high-risk patients. Ann Thorac Surg 2001;71(6):1964-8; Craver JM *et al.* Elective intra-aortic balloon counterpulsation for high-risk off-pump coronary artery bypass operations. Ann Thorac Surg 2001;71(4):1220-3).

There are, however, risks related to the use of IABs, particularly associated to the intra-luminal blood-contacting nature of the device. For example, a high risk of leg complications exist, as a relatively large tube and balloon must be inserted into the lumen of the groin (femoral) artery, typically less than 1 cm in diameter. Blood components, particularly platelets, are damaged by the action of the IAB. Female sex, smaller body mass and presence of peripheral vascular disease significantly increase the risk of complications (Lazar HL *et al.* Reduction of myocardial necrosis by positioning the intra-aortic balloon pump in the ascending aorta. Cardiovascular Surgery 1994;2(5):634-8).

Furthermore, introduction of the balloon can cause dislodgement of material from the lining of the aorta, or the balloon tip can perforate the aorta. The balloon can be misplaced, as its positioning is typically done without x-ray imaging. Paraplegia is a reported complication. The balloon can rupture and fill with blood, making its removal very difficult and fraught with complication. Groin hematomas can complicate removal of the device. (Cohen M *et al.* Sex and other predictors of intra-aortic balloon counterpulsation-related complications: prospective study of 1119 consecutive patients. Am Heart J 2000;139(2):282-7; Saito T *et al.* The calcified ascending aorta – preoperative evaluation and intraoperative management. Nippon Kyobu Geka 1992;40:118; Roma V *et al.* Atherosclerosis of the ascending aorta is an independent predictor of long-term neurologic events and mortality. J Am Coll Cardiol 1999;33:1308-16).

It is an object of the present invention to provide a new and improved method of performing off-pump coronary artery bypass surgery.

## Summary of the Invention

Accordingly, in a first aspect, the present invention provides a method for the conduct of a beating heart coronary artery bypass operation on a patient, the method including application of extra-aortic counterpulsation to the aorta of the patient for at least a part of the duration of the operation.

In a second aspect, the present invention provides a method of performing a coronary artery bypass operation on a patient's beating heart, said method comprising:

(a) preparing the patient for the operation;

(b) obtaining thoracic access;

(c) harvesting at least one appropriate conduit for grafting;

(d) wrapping an extra-aortic counterpulsation means with a connector tubing around the aorta proximal the heart, and attaching the connector tubing to pump means adapted to pump a fluid into the counterpulsation means;

(e) initiating counterpulsation in the extra-aortic counterpulsation means;

(f) bypassing a target coronary artery using a conduit harvested in step (c);

(g) repeating step (f) for each additional target coronary artery; and

(h) completing the operation as appropriate.

The method preferably also includes, after step (g), the step of removing the extra-aortic counterpulsation means from attachment to the aorta.

In preferred embodiments of the invention, the extra-aortic counterpulsation means includes an aortic compression means adapted, when actuated, to compress an aorta of a patient; a fluid reservoir; and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means in counterpulsation with the patient's heart. Such a extra-aortic counterpulsation means would comply fairly closely with the heart assist device disclosed in the Applicant's International PCT Patent Application No. PCT/AU 00/00654 (International Publication No. WO 00/76288).

In alternative embodiments, the extra-aortic counterpulsation means can be of any kind suitable for application during coronary artery bypass operations. Further examples of extra-aortic counterpulsation means potentially appropriate for use in accordance with the method disclosed herein include the external counterpulsation means described in US Patent No. 5554103, and the ventricular cardiac aid device with counter-pulsation disclosed in PCT Patent Application No. PCT/FR98/01631 (International Publication No. WO 99/04833), and the external counterpulsation apparatus disclosed in US Patent No. 4753226, among others.

Step (a) preferably includes, but is not limited to, administering a therapeutically effective amount of general anaesthesia to the patient; placing venous arterial lines for fluid administration and pressure monitoring; preparing an area of skin on the patient's chest with aseptic solution; preparing an operative field with sterile drapes positioned over the patient's chest; and inserting a transeosophageal echocardiography probe.

In preferred embodiments of step (b), thoracic access may be obtained by the performance of a partial sternotomy, a full sternotomy, a thoracotomy, port access or by any other appropriate method of gaining access to the patient's thorax. Once thoracic access has been obtained, a further step of assessing the patient's cardiac anatomy is preferably performed.

In further preferred embodiments of the invention, the conduits for grafting harvested in accordance with step (c) are typically the left internal mammary artery, the radial artery and/or the saphenous vein. In alternative embodiments, any other vessel appropriate for creating the requisite bypass may be used, including any other vessel taken from the patient's body or a synthetic graft.

In a preferred embodiment of the invention, the method further includes a first confirmation step comprising confirming the patient's suitability for the operation described herein including assessing the extent of any aortic disease and valve regurgitation. The first confirmation step is preferably performed prior to step (d). In cases where the first confirmation step suggests that the patient is not suitable for the operation described herein, the coronary artery bypass operation is performed in another way more suitable for the patient's condition.

In further preferred embodiments, when the extra-aortic counterpulsation means is wrapped around the aorta in accordance with step (d), it is wrapped around the ascending aorta.

In yet still further preferred embodiments, once wrapped around the aorta in the desired location, the extra-aortic counterpulsation means is secured in position using a suture or sutures. In alternative embodiments, securement of the counterpulsation means to the aorta is not achieved using a suture or sutures, but it is achieved using any other form of securing means that may be suitable.

Preferred embodiments additionally disclose that attaching the connector tubing to the pump means in accordance with step (d), further preferably includes attaching the connector tubing to a counterpulsation console, such as a Datascope 97 (Datascope Corp, Montvale, New Jersey, USA) or an Arrow ACAT (Arrow International Inc, Reading, Pennsylvania, USA). In alternative embodiments, the counterpulsation console is not limited to being one of those just disclosed, and can be any appropriate console such as, for example, a Helium driven counterpulsation console. In any of the embodiments just described, the pump may, of course, be a part (either integral with, or as a component) of a such a counterpulsation console.

Various baseline recordings that may be taken at any time throughout the operation preferably include, but are not limited to, systemic arterial pressure, left ventricular pressure and area loops, left main coronary artery flow and transcutaneous carotid doppler.

Preferred embodiments disclose that when counterpulsation is iniated in accordance with step (e), it is preferably set at a rate of 1:2 with respect to the patient's heart rate. In

other embodiments, however, counterpulsation may be set a rate of 1:1 with respect to the patient's heart rate, or at any other rate that is deemed to be appropriate for the purposes of the operation.

In yet still further preferred embodiments of the invention, immediately following step (e), the method includes a second confirmation step, said second confirmation step comprising confirming augmentation and timing settings. The second confirmation step additionally includes, but is not limited to, optimizing those augmentation and timing settings once they have been confirmed.

The second confirmation step may also be performed after each target coronary artery has been bypassed (after step (g), or after step (f) where there is only one target coronary artery).

In preferred embodiments, step (f) may include: applying a stabilizing arm to expose an area of the heart; using a snare upstream to occlude the target coronary artery; and opening the target coronary artery and suturing the conduit harvested as described above to the artery to create a distal anastomosis. Furthermore, for the purposes of completing step (f) (or steps (f) and (g)) preferred embodiments disclose that free coronary grafts may be sutured, stapled or otherwise attached proximally to the aorta on one, or the other, or both, of either side of the extra-aortic counterpulsation means, or to the mid-ascending aorta once the extra-aortic counterpulsation means has been removed. In alternative embodiments, free grafts may be attached end-to-side to a pedicled graft or other systemic arterial conduit.

Step (h) preferably includes, but is not limited to, checking hemostasis and hemodynamic stability; inserting chest drains; and closing the patient's chest and operative wound.

## Brief Description of the Drawings

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompany drawings in which:

Fig. 1 is a perspective view of the operative site during a coronary artery bypass operation being performed in accordance with the present invention; and

Fig. 2 is a schematic perspective view of a extra-aortic counterpulsation means positioned on the ascending aorta of the patient as disclosed by a preferred embodiment of the present invention;

## Detailed Description of the Preferred Embodiments

In a preferred embodiment, the method of the present invention of performing a coronary artery bypass operation on a patient's beating heart 12 comprises performing the following steps:

(a) preparing the patient for the operation. This step includes, but is not limited to, administering a therapeutically effective amount of general anaesthesia to the patient; placing of venous and arterial lines for fluid administration and pressure monitoring; preparing an area of skin on the patient's chest with aseptic solution; and preparing an operative field with sterile drapes positioned over the patient's chest;

(b) obtaining thoracic access. This is preferably performed by sternotomy. The patient's cardiac anatomy is then assessed.

(c) harvesting at least one appropriate conduit for grafting. Obviously, where there are a purality of target vessels, it may be necessary to harvest a number of conduits. Typical conduits appropriate for such grafting include the left internal mammary artery, the radial artery and/or the saphenous vein.

At this stage, or earlier, it is appropriate to perform a first confirmation step which comprises confirming the patient's suitability for the operation described herein including assessing the extent of any aortic disease and valve regurgitation. As discussed above, in cases where the first confirmation step suggests that the patient is not suitable for the operation described herein, the coronary artery bypass operation is performed in another way - perhaps in a more conventional way - which is more suitable for the patient's condition.

(d) wrapping an extra-aortic counterpulsation means 10 with a connector tubing around the aorta 11 proximal the heart 12, and attaching the connector tubing to an IABP such as that made by Datascope or Arrow International. The preferred position for the extra-aortic counterpulsation means 10 is around the ascending aorta 11. Further, once wrapped around the aorta 11 in the desired location, the extra-aortic counterpulsation means 10 is secured in position using a suture or sutures.

Preferred embodiments of the invention additionally disclose that the extra-aortic counterpulsation means 10 includes an aortic compression means adapted, when actuated, to compress the aorta 11 of the patient; a fluid reservoir; and a fluid pressure generating mean adapted to pump fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic means in counterpulsation with the patient's heart 12. Such a extra-aortic counterpulsation means 10 complies fairly closely with the heart assist device

disclosed in the applicant International PCT Patent Application No. PCT/AU 00/00654 (International Publication No. WO 00/76288).

(e) initiating counterpulsation in the extra-aortic counterpulsation means 10 at a rate of 1:2 with respect to the patient's heart rate.

In preferred embodiments of the invention, immediately following step (e), the method includes a second confirmation step, said second confirmation step comprising confirming augmentation and timing settings. The second confirmation step additionally includes, but is not limited to, optimizing those augmentation and timing settings once they have been confirmed.

The second confirmation step may also be performed after each target coronary artery has been bypassed (after step (g), or after step (f) where there is only one target coronary artery).

(f) bypassing a target coronary artery using a conduit harvested in step (c). This step may include: applying a stabilizing arm 13 to expose an area of the heart 12; using a snare upstream to occlude the target coronary artery; and opening the target coronary artery and suturing the conduit harvested as described above to the artery to create a distal anastomosis. Furthermore, for the purposes of completing step (f) (or steps (f) and (g)) preferred embodiments disclose that free coronary grafts may be sutured, stapled or otherwise attached proximally to the aorta on one, or the other, or both, of either side of the extra-aortic counterpulsation means, or to the mid-ascending aorta once the extra-aortic counterpulsation means has been removed.

If, of course, there are multiple target coronary arteries, steps (f) should be repeated as described by step (g) for each additional target coronary artery.

(h) removing the extra-aortic counterpulsation means 10 from attachment to the aorta 11; and

(i) completing the operation as appropriate. This step preferably includes, but is not limited to, checking hemostasis and hemodynamic stability; inserting chest drains; and closing the patient's chest and operative wound.

The patient is then returned to intensive care for post-operative monitoring.

<u>Pilot Clinical Study – Physiologic and observed effects on cardiovascular function</u>

Three male patients, with normal left ventricular function and ascending aortae, all with double or triple vessel coronary artery disease and suitable for OPCAB.

Pre-systolic unloading

In the pilot clinical study using the EAB-e to assess the efficacy of the current human cuff design, transosphageal echocardiography was used to measure the cross-sectional area of the left ventricle (mid-papillary line) at end systole and end diastole at baseline heart function and with the cuff counterpulsating at 1:1. Three separate data points were collected for each combination in each patient. Both end-diastolic and end systolic left ventricular sizes were seen to be consistently reduced by factors of 14% and 19%, respectively, with end-systolic size reducing proportionately more, indicating a 9% improvement in fractional area change also during 1:1 counterpulsation. The counterpulsation period was approximately 20 minute in each case.

The reduced LV diameter decreases the wall tension and reduces the level of myocardial oxygen consumption and the amount of work the heart must do. The reduced diameter allows cardiac myofibrils to make more forceful contractions, reflected in part in the improvement in fractional area change.

Diastolic augmentation

Furthermore, in the three pilot clinical studies, the counterpulsation effect has also been clearly demonstrated by measurement using transosophageal echocardiographic Doppler to determine left main coronary artery flow. Peak and mean velocity time integrals were measured at base line, and during 1:2 and 1:1 EAB-e counterpulsation. Three separate data points were collected at each setting in each of the patients. There was a consistent increase in both peak and mean coronary artery blood flow in diastole of the order of 30-50 %. This effect is not only seen against baseline measurements, but also seen in assisted versus unassisted beats (1:2 counterpulsation), further verifying the findings.

The effect of IAB counterpulsation on diastolic coronary artery blood flow is well documented in the clinical literature – flow improves from 20-120% by different methods of measurement, and typically in patients with low cardiac output in whom an IAB has

been placed for support. (Katz ES, Tunick PA, Kronzon I. Observations of Coronary Flow Augmentation and Balloon Function during intraaortic balloon counterpulsation using transesophageal echocardiography. Am J Cardiol 1992;69:1635-1639. Hutchison SJ, Thacker KB, Chandraratna PA. Effects of Intraaortic balloon counterpulsation on flow velocity in stenotic left main coronary arteries from transesophageal echocardiography. Am J Cardiol 1994;74:1063-1065).

It is important to note that the response of ventricular size and coronary flow to counterpulsation are dependant on the degree of heart failure – the worse the failure the greater the effect. (Richert CL, Koolen JJ, Visser CA. Transesophageal echocardiographic evaluation of left ventricular function during intraaortic balloon pump counterpulsation. J Am Echocardiography 1993;6:490-5. Katz ES, Tunick PA, Kronzon I. Observations of Coronary Flow Augmentation and Balloon Function during intraaortic balloon counterpulsation using transesophageal echocardiography. Am J Cardiol 1992;69:1635-1639. Hutchison SJ, Thacker KB, Chandraratna PA. Effects of Intraaortic balloon counterpulsation on flow velocity in stenotic left main coronary arteries from transesophageal echocardiography. Am J Cardiol 1994;74:1063-1065).

Safety re: embolism

In the clinical EAB-e in OPCAB pilot, as part of the safety assessment, particles in the carotid artery were counted using a Transcarotid Doppler Ultrasound. In the first three patients, there have been a total of 9, 12, and 0 counts seen during counterpulsation, and no patient has suffered any complication such as stroke. Emboli counts in OPCAB procedures are well documented to be of the order of 0-500, and in procedures using the heart-lung machine 500-2000.

In the acute preclinical EAB-e studies, ascending aortae from 8 pigs were examined by an independent pathologist both grossly and histologically. There was no evidence of structural damage to the wall or lining of the ascending aorta.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiments without departing from the spirit or scope of invention as broadly described. For example, the embodiments of the invention are not restricted for use with the embodiments of the heart assist device shown in PCT Patent Application No. PCT/AU/00/00654 (International Publication No. WO 00/76288). The specific embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Claims:

1. A method for the conduct of a beating heart coronary artery bypass operation on a patient, the method including application of extra-aortic counterpulsation to the aorta of the patient for at least a part of the duration of the operation.

2. A method of performing a coronary artery bypass operation on a patient's beating heart, said method comprising the steps of:

(a) preparing the patient for the operation;

(b) obtaining thoracic access;

(c) harvesting at least one appropriate conduit for grafting;

(d) wrapping an extra-aortic counterpulsation means with a connector tubing around the aorta proximal the heart, and attaching the connector tubing to pump means adapted to pump a fluid into the counterpulsation means;

(e) initiating counterpulsation in the extra-aortic counterpulsation means;

(f) bypassing a target coronary artery using a conduit harvested in step (c);

(g) repeating step (f) for each additional target coronary artery; and

(h) completing the operation as appropriate.

3. A method as claimed in claim 2, including, after step (g), the step of removing the extra-aortic counterpulsation means from attachment to the aorta.

4. The method as claimed in claim 2 or 3, wherein the extra-aortic counterpulsation means includes an aortic compression means adapted, when actuated, to compress an aorta of a patient; a fluid reservoir; and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means in counterpulsation with the patient's heart.

5. The method as claimed in claim 2 or 3, wherein the extra-aortic counterpulsation means is an external counterpulsation means or apparatus or a ventricular cardiac aid device with counter-pulsation.

6. The method as claimed in claim 3, 4 or 5, wherein step (a) includes administering a therapeutically effective amount of general anaesthesia to the patient; placing venous arterial lines for fluid administration and pressure monitoring; preparing an area of skin on the patient's chest with aseptic solution; preparing an operative field with sterile drapes positioned over the patient's chest; and inserting a transeosophageal echocardiography probe.

7. The method as claimed in any one of claims 2 to 6, wherein step (b), thoracic access is obtained by the performance of a partial sternotomy, a full sternotomy, a thoracotomy or port access.

8. The method as claimed in claim 7, wherein, once thoracic access has been obtained, a further step of assessing the patient's cardiac anatomy is performed.

9. The method as claimed in any one of claims 2 to 8, wherein the conduits for grafting harvested in accordance with step (c) are the left internal mammary artery, the radial artery and/or the saphenous vein.

10. The method as claimed in any one of claims 2 to 9, wherein the method further includes a first confirmation step comprising confirming the patient's suitability for the operation described herein including assessing the extent of any aortic disease and valve regurgitation.

11. The method as claimed in claim 10, wherein the first confirmation step is performed prior to step (d).

12. The method as claimed in any one of claims 2 to 11, wherein, when the extra-aortic counterpulsation means is wrapped around the aorta in accordance with step (d), it is wrapped around the ascending aorta.

13. The method as claimed in any one of claims 2 to 12, wherein, once wrapped around the aorta in the desired location, the extra-aortic counterpulsation means is secured in position using a suture or sutures.

14. The method as claimed in any one of claims 2 to 13, wherein, attaching the connector tubing to the pump means in accordance with step (d), further includes attaching the connector tubing to a counterpulsation console.

15. The method as claimed in any one of claims 2 to 14, wherein various baseline recordings are taken at any time throughout the operation.

16. The method as claimed in claim 15, wherein the baseline recordings include one or more of systemic arterial pressure, left ventricular pressure and area loops, left main coronary artery flow and transcutaneous carotid doppler.

17. The method as claimed in any one of claims 2 to 16, wherein, when counterpulsation is initiated in accordance with step (e), it is set at a rate of 1:2 with respect to the patient's heart rate.

18. The method as claimed in any one of claims 10 to 17, wherein immediately following step (e), the method includes a second confirmation step comprising confirming augmentation and timing settings.

19. The method as claimed in claim 18, wherein the second confirmation step additionally includes optimizing those augmentation and timing settings once they have been confirmed.

20. The method as claimed in claim 18 or 19, wherein the second confirmation step is also performed after step (g), where each target coronary artery has been bipassed, or after step (f) where there is only one target coronary artery.

21. The method as claimed in any one of claims 2 to 20, wherein, step (f) includes: applying a stabilizing arm to expose an area of the heart; using a snare upstream to occlude the target coronary artery; and opening the target coronary artery and suturing the conduit harvested as described above to the artery to create a distal anastomosis.

22. The method as claimed in claim 21, wherein for the purposes of completing step (f) (or steps (f) and (g)), free coronary grafts are sutured, stapled or otherwise attached proximally to the aorta on one, or the other, or both, of either side of the extra-aortic counterpulsation means, or to the mid-ascending aorta once the extra-aortic counterpulsation means has been removed.

23. The method as claimed in claim 22, wherein free grafts are attached end-to-side to a pedicled graft or other systemic arterial conduit.

24. The method as claimed in any one of claims 2 to 23, wherein step (h) includes one or more of checking hemostasis and hemodynamic stability; inserting chest drains; and closing the patient's chest and operative wound.

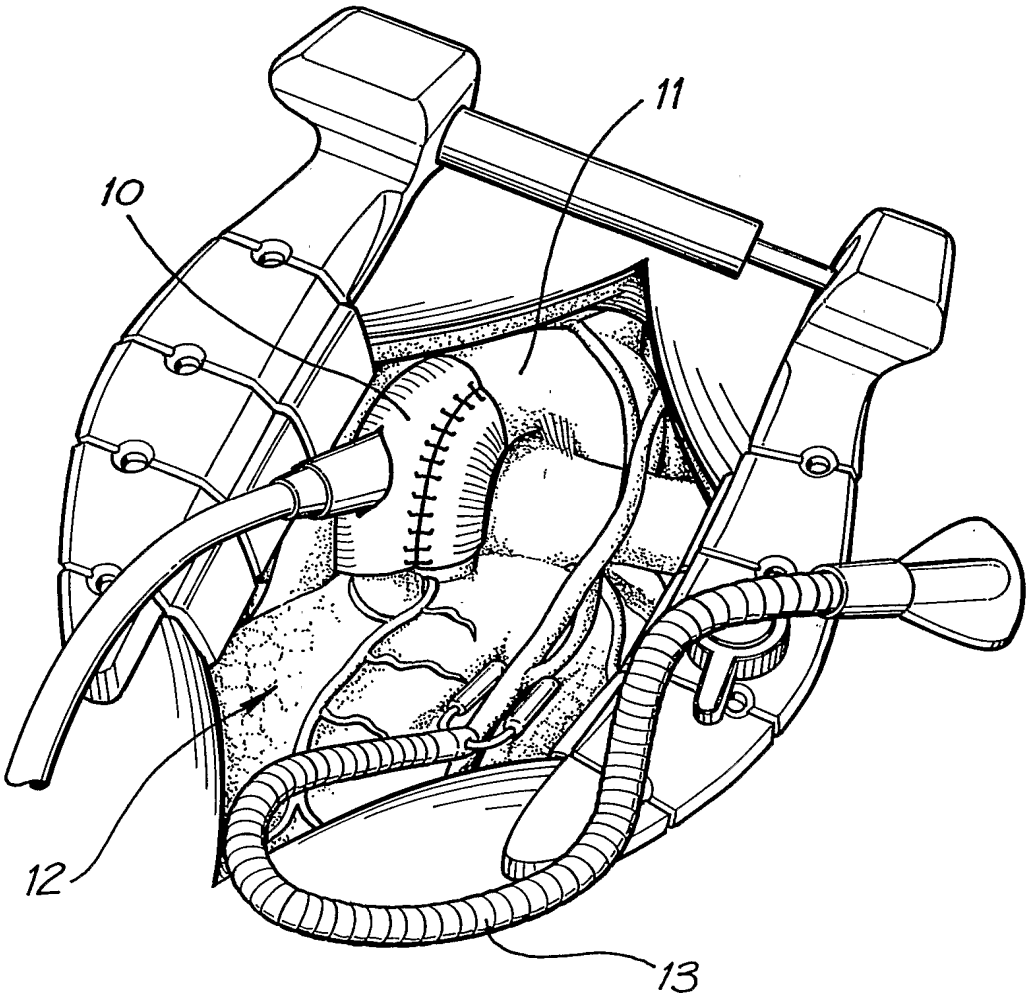


FIG. 1

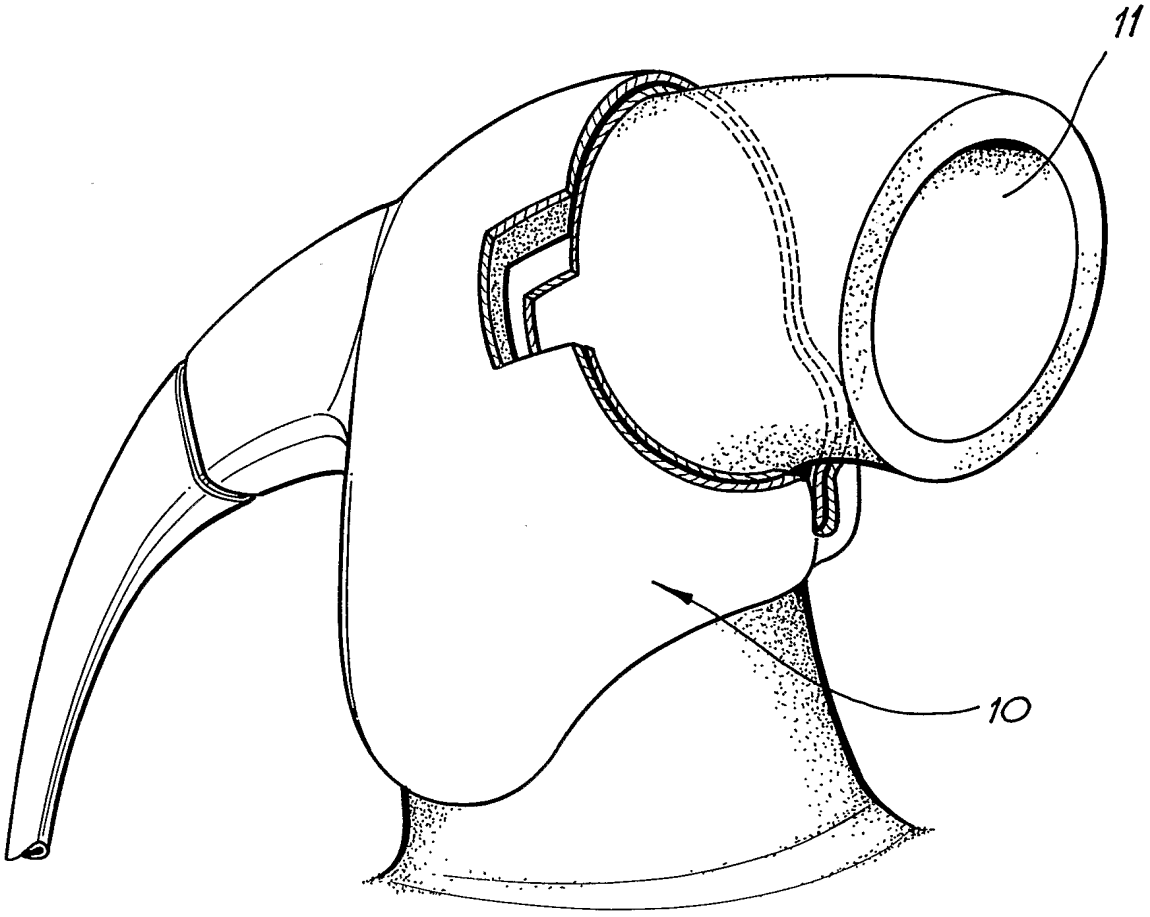


FIG. 2

**INTERNATIONAL SEARCH REPORT**

International application No.
**PCT/AU02/01277**

**A. CLASSIFICATION OF SUBJECT MATTER**

Int. Cl. [7]: A61M 1/10

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
SEE ELECTRONIC DATABASES CONSULTED

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI JAPIO MEDLINE: coronary heart cardio bypass beating active off-pump extra-aortic counter compress pump pressure extra assist aid augment aort artery off-pump

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5554103 A (ZHENG et al) 10 September 1996<br>Claims | 1 |
| X | WO 99/04833 A1 (COMMISSARIAT A L'ENERGIE ATOMIQUE) 4 February 1999<br>Abstract and figures | 1 |
| X | WO 00/76288 A2 (SUNSHINE HEART COMPANY PTY LTD) 21 December 2000<br>Entire document | 1 |

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 November 2002 | 25 NOV 2002 |
| Name and mailing address of the ISA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized officer<br>**MATTHEW FORWARD**<br>Telephone No : (02) 6283 2606 |

## INTERNATIONAL SEARCH REPORT

International application No.
**PCT/AU02/01277**

**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| P,X | WO 02/24255 A1 (SUNSHINE HEART COMPANY PTY LTD) 28 March 2002<br>Page 3 | 1 |
| X | Gabbay et al (1981), The Extra-Aortic Balloon Counterpulsation as an Assist Device: Transactions-American Society for Artificial Internal Organs, V27, pp598-603<br>Entire document | 1 |
| A | Bowles et al (1991), Development of mock circulation models for the assessment of counterpulsation systems: Cardiovascular Research: V25(11): pp 901-908 | |
| A | Sinclair et al (2000), Extra-Anatomic Redo of MIDCAB and OPCAB: An Early Experience. The Heart Surgery Forum, V3(2), pp127-133<br>Abstract | |
| P,A | Detter et al (2002), Comparison of Two Stabilizer Concepts for Off-Pump Coronary Artery Bypass Grafting. Annals of Thoracic Surgery, V74, pp497-501<br>Abstract and figure 1 | |
| P,A | Abu-Omar et al (2002), Off-pump coronary artery bypass grafting. Lancet, V360, pp327-329 | |
| P,A | Couture et al (2002), Mechanisms of Hemodynamic changes during off-pump coronary artery bypass surgery. Canadian Journal of Anesthesia, V49:8, pp835-849 | |

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
**PCT/AU02/01277**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| US | 5554103 | AU | 38394/93 | AU | 10068/97 | CA | 2095690 |
| | | CN | 1078136 | EP | 569308 | FI | 932059 |
| | | IL | 105633 | JP | 6-292721 | NO | 931649 |
| | | US | 5997540 | | | | |
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END OF ANNEX